

Trigger-Flex[®] Dart

Lumbar Procedure Technique ^{1, 2, 3}

The following information is intended to be used as a guide and should not be considered a substitute for surgical qualifications required to perform discectomy procedures or for training in the use of the Trigger-Flex[®] Dart.

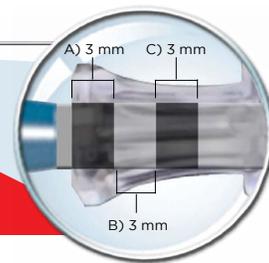
Recommended Setting: Bipolar Turbo 10

Recommendations:

- Only use the 16 gauge spine needle supplied by Elliquence, LLC. Recommended use of needle is one per spine level.
- Elliquence, LLC. always recommends a dry run prior to a live case or knowledge and experience of a lumbar disc procedure.
- Please refer to the IFU packaged with the product for a complete list of warnings and precautions.

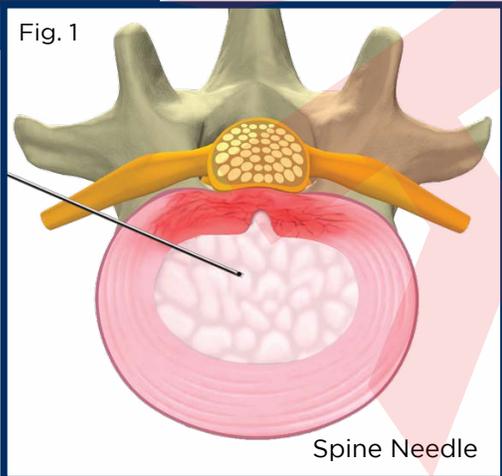
Depth Markings

- A) 3 mm
- B) 3 mm
- C) 3 mm



Step 1

Fig. 1



Step 1: Placement of 16g Spine Needle

Under fluoroscopic guidance a 16g spinal needle is inserted into the nucleus pulposus using Kambin's triangle. The end of the needle should be in the proximal midline of the disc.



Infuse approximately 1ml of saline without any pressure, making sure saline is filled to the top of the needle port.

Caution: To prevent insertion too close to the spinal cord and end plates observe Dart tip under fluoroscopic guidance and do not go further than the posterior 1/3 of the disc nucleus.

Step 2

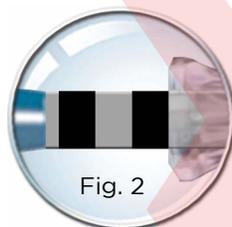
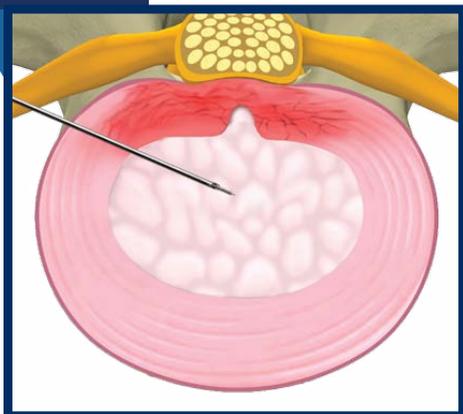


Fig. 2

STEP 2: Initial Positioning of Trigger-Flex[®] Dart

Insert the Trigger-Flex[®] Dart into the needle, while keeping the needle fixed until you reach the end of black depth marking C (as shown in fig 2).

Step 3

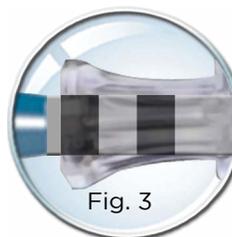
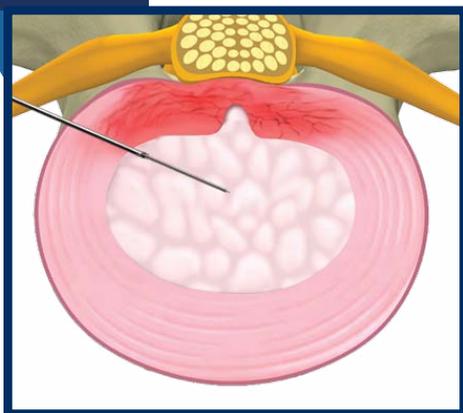


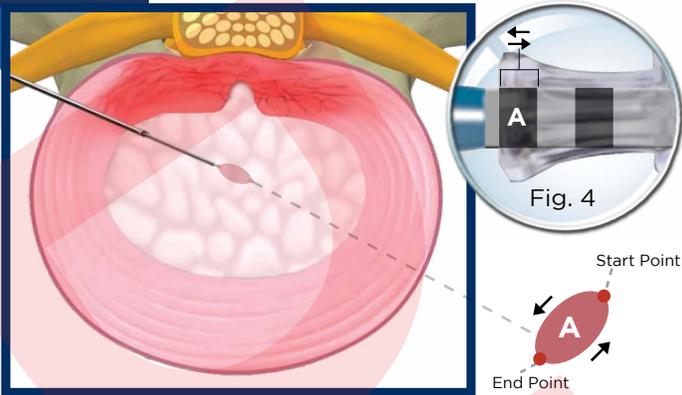
Fig. 3

STEP 3: Initial Positioning of 16g Spine Needle

While keeping the Trigger-Flex[®] Dart Device fixed pull the needle back to the anterior of the disc (as shown in fig 3).

Caution: The tip extends 10mm past the edge of the needle.

Step 4

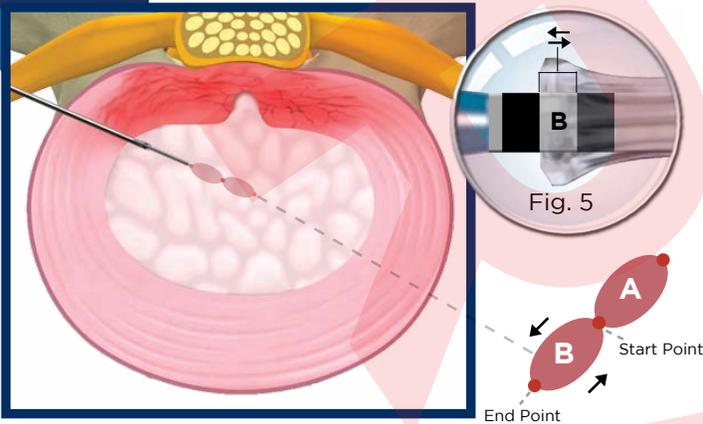


STEP 4: Ablation of Cavity A

Set the Bipolar Turbo Setting to 10. Keep the Needle in a fixed position. While at the initial positioning of the Trigger-Flex® Dart, activate the Dart using the Bipolar Turbo (Black) foot pedal and move the Dart Anteriorly (out) and Posteriorly (in) within the beginning and end of the 3mm black depth marking A (shown in fig 4) to create cavity A. Do this at a rate of 1 second per stroke in each direction for a total of 5 strokes (total 5 seconds per cavity). Place Dart back. Wait 5 seconds before moving to step 5.

Caution: Serious nerve injury or paraplegia may occur if the spinal cord or nerve root come into direct contact with the tip of the Dart device during activation. When performing ablation with the Dart device, stop the procedure if the patient complains of sudden onset of pain.

Step 5

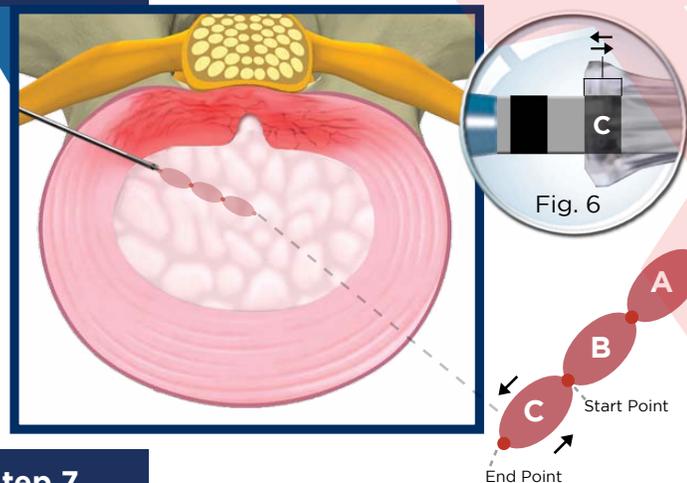


STEP 5: Ablation of Cavity B

Reposition: Pull the Trigger-Flex® Dart Anteriorly (out) until you reach the next 3mm depth marking B (shown in fig 5).

Activation: Keep the Needle in a fixed position. Activate the Trigger-Flex® Dart using the Bipolar Turbo (Black) foot pedal and move the Dart Anteriorly (out) and Posteriorly (in) within the beginning and end of the 3mm grey marking B (shown in fig 5) to create cavity B. Do this at a rate of 1 second per stroke in each direction for a total of 5 strokes (total 5 seconds per cavity). Wait 5 seconds before moving to step 6.

Step 6

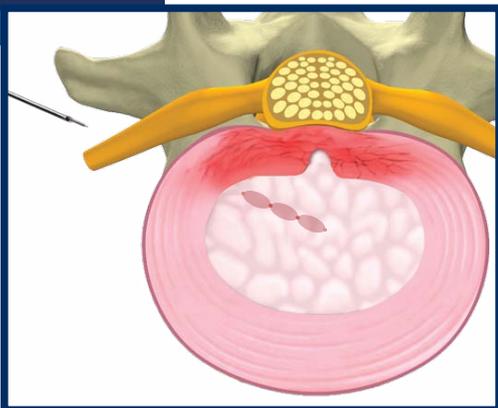


STEP 6: Ablation of Cavity C

Reposition: Pull the Trigger-Flex® Dart Anteriorly (out) to the final 3mm black depth marking C (shown in fig 6).

Activation: Keep the Needle in a fixed position. Activate the Trigger-Flex® Dart using the Bipolar Turbo (Black) foot pedal and move the Dart Anteriorly (out) and Posteriorly (in) within the beginning and end of the 3mm black marking C (shown in fig 6) to create cavity C. Do this at a rate of 1 second per stroke in each direction for a total of 5 strokes (total 5 seconds per cavity).

Step 7



STEP 7: Removal of the Needle and Trigger-Flex® Dart

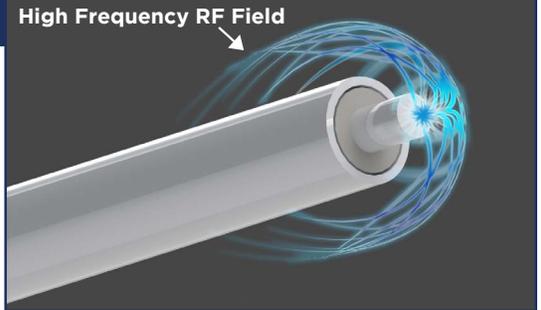
Caution: Do not withdraw the Trigger-Flex® Dart device while it is being activated.

Carefully remove the Needle and Trigger-Flex® Dart under fluoroscopic guidance.

Energy Disbursement

Elliquence LLC. proprietary bipolar energy works by creating a pure High Frequency RF Plasma field of energy that alternates flow between the tip to the outer Dart cannula.

This energy field has the ability to break down soft tissue at low temperature in order to have a safe and controlled volume reduction, creating the cavity in the targeted area to gradually decompress the lumbar disc.



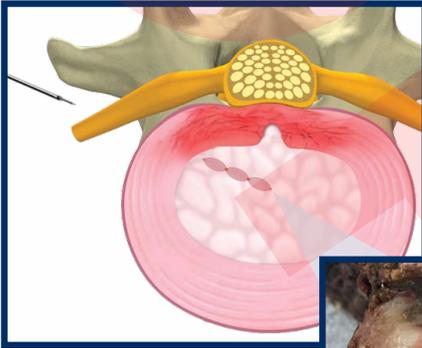
Ablation and Thermal Study

Fig. 7

Nucleus Tissue Ablation:

Dissolving Targeted Tissue Volume.
(As shown in Fig. 7.)

When ablating the nucleus, the thermal spread is indicated below in the internal nucleus thermal study and thermal image.
(As shown in Fig. 8.)



Approximate Pocket Sizes

Length: 9mm
Height: 1.8mm

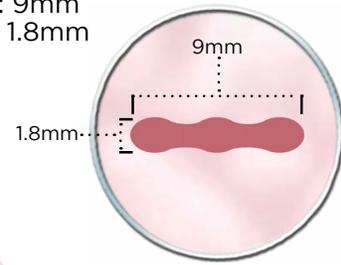
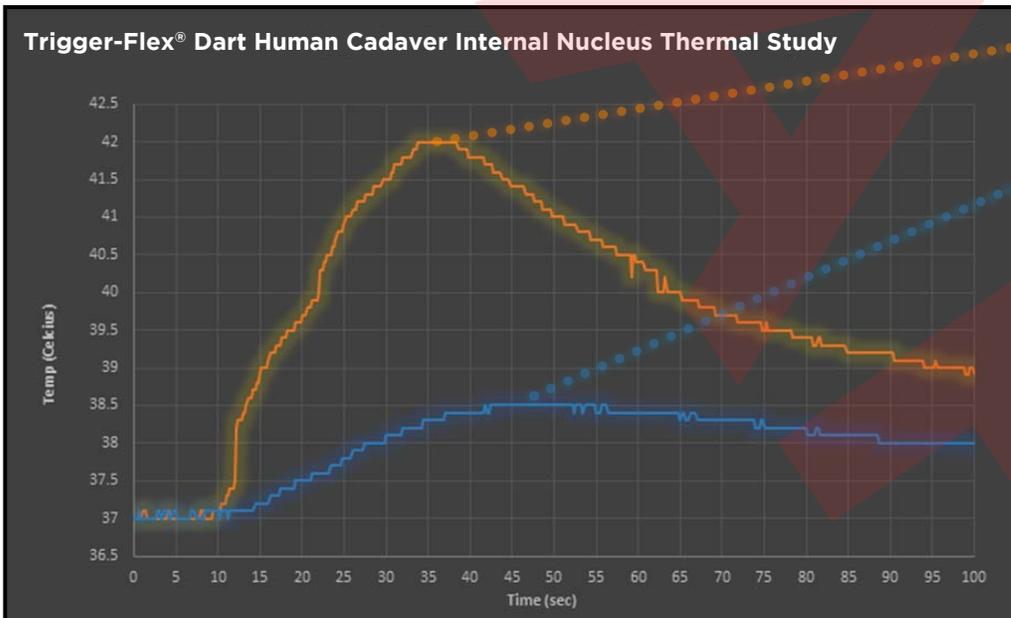


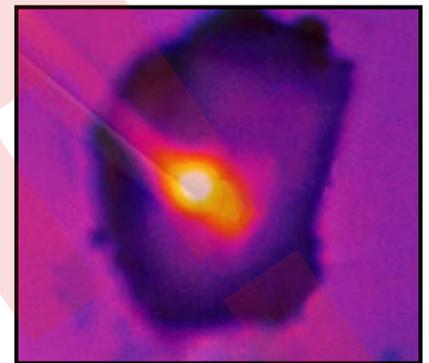
Fig. 8

Trigger-Flex® Dart Human Cadaver Internal Nucleus Thermal Study



Probe Temp 1 (1mm)
Max 42°C

Probe Temp 2 (3.7mm)
Max 38.5°C



References:

- 1) Performance has not been specifically established in all procedures.
- 2) TR 20160927-1
- 3) The following information is intended to be used as a guide and should not be considered a substitute for surgical qualifications required to perform discectomy procedures or for training in the use of the Trigger-Flex® Dart.

Warning and precautions:

- A) Hazardous electrical output. This equipment is for use only by qualified personnel.
- B) Only elliquence supplied and/or approved accessories should be used to ensure proper operation. The elliquence generator and its accessories are identified with the manufacturer information and reference identification number for proper traceability.
- C) Read the instruction manual in detail before use.
- D) Use of accessories or cables other than elliquence specified, as replacement parts for internal components, may result in increased emissions or decreased immunity of the elliquence RF generator.
- E) The coupling of any non-elliquence manufactured product, with an elliquence manufactured product invalidates all elliquence product warranties and all elliquence legal liabilities associated with such use.

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